K041892

FEB - 4 2005

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
Worldwide Headquarters
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Sean Reynolds
(978) 421-9655, Ext. 9386

Date Summary Prepared:

June 28, 2004

Device:

ZOLL AED ***Pro*** External Defibrillator

Classification:

Defibrillator, Low-energy – DC: Class II (21 CFR 870.5300)

Automatic External Defibrillators; Class III (21 CFR 870.5310)

Cardiac Monitors (including Cardiotachometers and Rate Alarms): Class II (21 CFR 870.2300

Substantial Equivalence:

The features and functions of the ZOLL AED ***Pro*** External Defibrillator are substantially equivalent to those of the ZOLL AED Plus with CPR Aid: 510(k) No. K011541, cleared 4/11/2002, the ZOLL AED Plus: 510(k) No. K033474, cleared 5/21/2004 and the Philips Medical Systems, Heartstart FR2+ (formerly Heartstream ForeRunner), 510(k) No. K013425, cleared 1/14/2002.

Description:

The ZOLL AED ***Pro*** External Defibrillator is a portable, battery powered, automated external defibrillator (AED) that uses voice prompts and visual messages to provide feedback to a user attempting a cardiac arrest rescue. The AED ***Pro*** acquires and analyzes an adult or pediatric patient's ECG signal and, if a shockable rhythm is detected, recommends delivery of a defibrillation shock via voice and visual prompts.

510(k) Summary

Defibrillation therapy is provided by using defibrillation electrode products specifically designed to be attached to the ZOLL AED ***Pro.*** ZOLL ***pedi•padz™ II*** defibrillation electrodes enable users to provide therapy to children less than 8 years of age. When used in conjunction with ZOLL **CPR-D•*padz*™**, the AED ***Pro*** provides CPR compression performance feedback to the user through voice prompts.

The ZOLL AED ***Pro*** also provides a non-diagnostic ECG monitoring feature and manual override capabilities for physicians and appropriately trained healthcare providers. A high-resolution LCD Screen will display ECG Data, Visual Prompts, Shock Count and CPR compression performance.

Intended Use

The ZOLL AED Pro External Defibrillator is a portable, ruggedized, automated external defibrillator intended for use by personnel who are trained in basic life support, advanced life support, or other physician-authorized emergency medical response who must respond to emergency situations, to deliver defibrillation therapy and to display ECG rhythms of patients during treatment.

Comparison of Technological Characteristics:

The ZOLL AED ***Pro*** design characteristics are the same as those of the indicated predicate devices; the technology is very similar to that of the ZOLL AED *Plus*. The ZOLL AED ***Pro*** acquires and analyzes ECG signals and provides shock advisory determinations for adult and pediatric patients. The ZOLL AED ***Pro*** advises users to deliver a shock, perform CPR or conduct patient assessment through audible and visual prompts identical to those used by the ZOLL AED *Plus*. The AED ***Pro*** ECG monitoring feature and manual override capability are substantially equivalent to that of the Philips Heartstart FR2+ defibrillator.

Performance Testing:

The ZOLL AED ***Pro*** External Defibrillator has been subjected to extensive performance testing to ensure that the device meets all of its functional requirements and performance specifications. Safety testing was performed to assure the device complies with applicable sections of recognized industry and safety standards.

Conclusion

Based on the results of the performance and safety testing, the ZOLL AED ***Pro*** has demonstrated that its features, functions and incorporated interpretive algorithm are substantially equivalent to that of the indicated commercially distributed predicate devices with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2005

Mr. Sean Reynolds
Regulatory Affairs Engineer
Zoll Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105

Re: K041892
Trade/Device Name: ZOLL AED *Pro* External Defibrillator
Regulation Number: 21 CFR 870.5310
Regulation Name: Automatic External Defibrillator
Regulatory Class: III
Product Code: MJK
Dated: December 3, 2004
Received: December 6, 2004

Dear Mr. Reynolds:

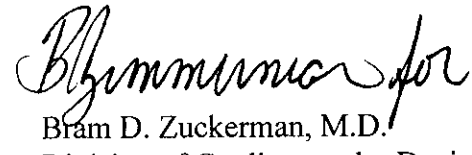
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Division of Cardiovacsular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): K041892

Device Name: ZOLL AED Pro External Defibrillator

Indications for Use

Use of the device for defibrillation is indicated on victims of cardiac arrest with apparent ***lack of circulation*** as indicated by:

- Unconsciousness, and
- Absence of normal breathing, and
- Absence of a pulse or signs of circulation.

When the victim is less than 8 years of age or weighs less than 55 lbs (25 kg), the AED Pro unit should be used with ZOLL ***pedi•padz™ II*** defibrillation electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

At the discretion of the rescuer, the Monitoring Mode feature can be used with the AED ***Pro*** ECG Cable to provide a non-diagnostic display of a breathing or responsive patient's ECG rhythm, regardless of their age. While connected to the AED ***Pro*** ECG Cable, the AED ***Pro*** performs a background analysis of the patient's rhythm and disables its defibrillator feature.

Contraindications for Use — Defibrillation

Do not use the AED Pro unit for defibrillation when the patient

- Is conscious; or
- Is breathing; or
- Has a detectable pulse or other signs of circulation.

Contraindications for Use — CPR Monitoring

The CPR monitoring function is not intended for use on patients under 8 years of age.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

B Gramiuma Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number k041892